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A dose-escalation clinical trial to evaluate the safety and immunogenicity of a replication-defective HIV-1 vaccine-HIVAX

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Background

Replication-defective SIV elicited protective immunity in animals. In this first-in-human therapeutic vaccination study, a replication-defective HIV-1 vaccine was tested in HIV-1 infected subjects under antiretroviral therapy.

Methods

A010 is an ongoing randomized, placebo-controlled dose-escalation clinical trial to evaluate the safety and the immunogenicity of two doses of a replication defective HIV-1 vaccine (HIVAX™) in subjects receiving stable highly active antiretroviral therapy (HAART) who have an HIV-1 RNA <50 copies/ml and CD4 cell count >500 cells/mm3. Following the randomized placebo-controlled vaccination phase subjects who received active vaccine and who meet eligibility will undergo a 12-week analytical antiretroviral treatment interruption.

Results

HIVAX™ is well tolerated in HIV infected subjects. Only mild injection site reaction occurred with transient duration. No medical treatment is necessary. High level of cell-mediated immune responses measured by ELISPOT assay was noticed after vaccination.

Conclusion

The replication defective HIV vaccine appears no severe adverse effect in HIV-1 infected subjects. High level of cell-mediated immune response was elicited in the vaccinees. HIVAX™ is worth for further evaluation of protective efficacy.

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